

10



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,168	11/22/2000	R. Terry Dunlay	97,022-G1	5283
7590 04/07/2004 McDonnell Boehnen Hulbert & Berghoff Suite 3200 300 South Wacker Drive Chicago, IL 60606			EXAMINER CHEU, CHANGHWA J	
			ART UNIT 1641	PAPER NUMBER

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/721,168

**Applicant(s)**

DUNLAY ET AL.

**Examiner**

Jacob Cheu

**Art Unit**

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-15, 21-25 and 28-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15, 21-25, 28-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1641

### **DETAILED ACTION**

1. Applicant's amendment filed on 1/4/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1-12, 16-20, 26-27 are cancelled.
2. Claims 28-31 are added to the instant application.
3. Currently, claims 13-15, 21-25, 28-31 are under examination.

### ***Priority***

2. Applicant amends the specification to correct the priority of the instant application from 4/16/1999 to 2/27/1997. Applicant points out that the current application having the effective filing date on 11/22/2000 which is not subject to the new 37 CFR 1.78 (a)(2) and (a)(5) where the effective date is after the 11/29/2000. The examiner agrees that the instant application can be benefited from the earliest parent application filing date on 2/27/1997. Accordingly, the correction on the priority has been entered into record.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

Art Unit: 1641

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 13-15, 21-25, 28-31 are rejected under the judicially created doctrine of double patenting over claims 1-28 of U. S. Patent No. 6620591 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:

The instant invention recites a method of for analyzing distribution of a protein of interests between cell membrane and cell cytoplasm with the main features of (a) cells containing use of fluorescent reporter molecules that report on each of the cell cytoplasm, the cell membrane, and a protein of interest', (b) creating cell cytoplasm masks and cell membrane masks', (c) measuring fluorescent intensity of the fluorescent signals from the fluorescent reporter molecule that reports on the protein of interest in the cell cytoplasmic and cell membrane masks; or (d) making the calculations of intensity ratio from each component, where the image data can be stored in the database. The U.S. Patent (6620591) recites a similar method of detecting translocation, i.e. distribution, of a cellular component of interests between a cellular compartment and a second component on or within individual cells. The first cellular component and second cellular component is cell cytoplasm and cell membrane, respectively. (See claims 1, 10) Both methods recited in the instant application and the US Patent (6620591), the images data can be stored in the database, and the proteins of interests include GTP protein, kinase, Rho family protein.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 13-15, 21-25, 28-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 13, step (b), line 6, "molecules that report on cell membrane are used to create cell *cytoplasmic* masks of individual cells" is vague and indefinite. Examiner believes that the "cell cytoplasmic masks" should "cell membrane masks" since it would be consistent with the recited step (c) and (d)(i) in measuring cytoplasmic and membrane mask. Clarification is needed.

With respect to claim 13, step (d)(i), line 3, "cytoplasmic mask and the cell membrane mask; *and*" is vague and indefinite. Since the calculation is based on the *one or both* the two parameters, namely ratio intensity and/or the difference of the intensity, it is suggested that applicant changes "and" to "and/or" for consistency.

With respect to claims 29-31, there is no "the digital data" in claim 13, accordingly, claims 29-31 are rejected due to lack of antecedent basis.

***Response to Applicant's Argument***

7. Applicant's amendments on both claims and priority have over the prior arts cited in the previous Office Action under 35 U.S.C §103 (a), as unpatentable over Morrioso et al. (US 5869238) in view of Walt et al. (US 6210910). Particularly, the priority date of this instant application has been corrected as 2/27/1997, thus antedated the secondary reference of Walt et al.

Art Unit: 1641

(effective date is 3/2/1998). Accordingly, examiner is hereby withdrawn the rejections under 35 U.S.C §103 (a) set forth in the previous Office Action.

***Allowable Subject Matter***

8. The following is an examiner's statement of reasons for allowance:

No prior art teaches or suggests a method of detecting the distribution of a protein of interests between cell membrane and cell cytoplasm by the instant recited method. The closest prior art is the Morrison et al. reference (US 5869238) but Morrison et al. do not teach the special features recited in this invention including, (a) cells containing use of fluorescent reporter molecules that report on each of the cell cytoplasm, the cell membrane, and a protein of interest', (b) creating cell cytoplasm masks and cell membrane masks', (c) measuring fluorescent intensity of the fluorescent signals from the fluorescent reporter molecule that reports on the protein of interest in the cell cytoplasmic and cell membrane masks; or (d) making the calculations of intensity ratio from each component, where the image data can be stored in the database.

Applicant is invited to clarify the indefiniteness and vagueness on claims 13-15, 21-25, 28-31 as outlined in this Office Action. Furthermore, applicant is invited to consider the obvious-typed double patenting issue set forth in this Office Action.

***Conclusion***

9. No claim is allowed.
10. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1641

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu

Examiner

Art Unit 1641

March 31, 2004

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

02/05/04